

K052623

**Summary of Safety and Effectiveness  
Imageless Hip Module for the StealthStation® System**

**I. Manufacturer**

Medtronic Navigation, Inc.  
826 Coal Creek Circle  
Louisville, Colorado 80027 USA  
Telephone Number: (720) 890-3217  
Fax Number: (720) 890-3517

MAR 2 2006

**II. Contact**

Tina Dreiling  
Associate Regulatory Affairs Specialist  
Medtronic Navigation, Inc.

**III. Product Name / Classification**

Common Name: Stereotaxic instrument  
Classification Name: Instrument, Stereotaxic  
Trade Name: Imageless Hip Module for the StealthStation® System  
Stereotaxic instrument - Class II as described in 21 CFR § 882.4560  
Product Code: HAW

**IV. Date Summary Submitted**

September 22, 2005

**V. Description of Device Modification**

The Imageless Hip Module for the StealthStation® System is the Imageless Hip Module provides a mechanism that enables the establishment of stereotactic coordinates without the use of a pre-operative or intra-operative images.

**VI. Substantial Equivalence**

The Imageless Hip Module for the StealthStation® System is substantially equivalent to the Hip Module for the StealthStation® System (K021980).

The only difference between the Hip Module for the StealthStation® System and the Imageless Hip Module for the StealthStation® System is the Imageless Hip Module provides a mechanism that enables the establishment of stereotactic coordinates without the use of a pre-operative or intra-operative images. In addition, the substantial equivalence for this application is established with the accuracy testing provided in this filing. As required by risk analysis, all verification and validation activities performed by designated individuals and the results demonstrated substantial equivalence.

**VII. Indications for Use**

The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Imageless Hip Module for the StealthStation® is intended to precisely position instruments and implants in example procedures such as but not limited to:

Orthopedic Procedures:

Minimally Invasive Orthopedic Procedures

Total Hip Replacement (Primary and Revision)

Tumor Resection and Bone/Joint Reconstruction

Placement of Iliosacral Screws

Femoral Revision

Stabilization and Repair of Pelvic Fractures (Including But Not Limited to Acetabular Fractures)



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**

**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

**MAR 2 2006**

Medtronic Navigation, Inc.  
c/o Ms. Tina Dreiling  
Associate Regulatory Affairs Specialist  
826 Coal Creek Circle  
Louisville, Colorado 80027

Re: K052623

Trade/Device Name: Imageless Hip Module for the StealthStation® System  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: II  
Product Code: HAW  
Dated: February 2, 2006  
Received: February 3, 2006

Dear Ms. Dreiling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Ms. Dreiling

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Melkerson", with a stylized initial "M" and a trailing flourish.

Mark N. Melkerson, M.S.

Acting Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K052623

Device Name: Imageless Hip Module for the StealthStation® System

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Stabilization and Repair of Pelvic Fractures (Including But Not Limited To Acetabular Fractures)

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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**510(k) Number** K052623